

Application No. 10/699,683  
Amdt. dated January 21, 2005  
Reply to Office Action of October 21, 2004

3

### REMARKS/ARGUMENTS

In the Office Action, the Examiner rejected claims 19, 22, 25 and 27 to 28 under 35 USC 102(e) as being anticipated by Gurtiss III.

Claim 19 is directed to an attenuated strain of a bacterium harbouring a vector comprising a nucleic acid molecule encoding at least one immunoprotection-inducing *Chlamydia* protein or a fragment thereof which generates a *Chlamydia* protein specific immune response and a promoter operatively coupled to the nucleic acid molecule for expression of *Chlamydia* protein or fragment thereof in cells of a host to which the strain is administered but not in the attenuated bacteria. Claims 22, 25 and 27 to 28 are dependent, directly or indirectly, on claim 19.

As is explained in the specification, for example, on page 8, lines 7 to 15, an important feature of the invention is that the primary immunization is effected by administration of an attenuated bacterial vector, wherein the transfected DNA is not expressed in the bacterial vector. The expression of the primary DNA is effected when the bacterial vector has released the DNA into the appropriate host cells, such as macrophages or dendritic cells. After uptake of the bacterial vector by the cells, the auxotrophic bacteria dies and the plasmid DNA then is released into the cytoplasm of the infected host cells and the encoded gene expressed in the host cells.

In this regard, it is noted that claim 19 specifically refers to the *Chlamydia* protein being expressed in the host but not in the attenuated bacteria.

This application is a division of US Patent Application No. 09/453,289, which has now issued as USP 6,676,949 over the Gurtiss III reference. The claims of the parent case are directed to a method of immunizing a host using an initial administration of an attenuated bacteria defined in the same manner as in claim 19 of this application.

Application No. 10/699,683  
Amdt. dated January 21, 2005  
Reply to Office Action of October 21, 2004

4

The Gurtiss III reference was extensively discussed in the prosecution of the parent application. Gurtiss III is concerned with a method of stimulating an immune response caused by a pathogen to produce an antigen capable of inducing an immune response in the vertebrate or invertebrate against the pathogen. Thus, in Gurtiss, the avirulent microbe directed the expression of the foreign antigen in the avirulent microbe. There is no suggestion in Gurtiss as to any other form of antigen expression. It is noted that the earliest date of filing of Gurtiss predated any notion of DNA immunization to effect foreign gene expression in a host to which an expression vector is administered.

It is submitted that there exists a fundamental difference between the attenuated bacteria defined in applicants claims and the Gurtiss reference. In the present invention, the attenuated bacteria is employed as a carrier for the vector and it is the promoter in the DNA construct which directs expression of the MOMP in the host cells only and not in the attenuated bacteria, quite the reverse of Gurtiss.

Accordingly, it is submitted that claims 19, 22, 25 and 27 to 28 are not anticipated by Gurtiss III and hence the rejection thereof under 35 USC 102(e) should be withdrawn.

The Examiner rejected claims 20 to 21, 24 and 26 under 35 USC 103(a) as being unpatentable over Gurtiss III as applied to claims 19, 22, 25, 27 to 28, in view of Brunham (WO 98/02546).

The Examiner relies on Brunham for teaching relating to the nucleic acid that encodes a protective MOMP or MOMP fragment of *Chlamydia*, wherein the MOMP nucleic acids were obtained from *C. trachomatis* and incorporated into pcDNA3. In addition, Brunham is relied on for teaching the use of cytomegalovirus promoter in association with the MOMP nucleic acid is an analogous art.

Application No. 10/699,683  
Amdt. dated January 21, 2005  
Reply to Office Action of October 21, 2004

5

These features are features of the subsidiary claims the subject of this rejection. However, the Examiner does not refer to any teaching of Brunham which would remedy the basic defects of Gurtiss as discussed above.

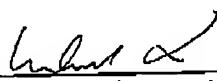
Accordingly, it is submitted that claims 20 to 21, 24 and 26 are patentable over the applied combination of prior art and hence the rejection thereof under 35 USC 103(a) as being unpatentable over Gurtiss III in view of Brunham, should be withdrawn.

The reference to related applications on page 1 has been updated with respect to the status of the parent case.

We are enclosing a copy of the missing reference from the IDS submitted October 26, 2004.

It is believed that this application is now in condition for allowance and early and favourable consideration and allowance are respectfully solicited.

Respectfully submitted,

  
\_\_\_\_\_  
Michael I. Stewart  
Reg. No. 24,973

Toronto, Ontario, Canada,  
(416) 595-1155  
FAX No. (416) 595-1163